SUMMARY OF THE
QUALITY SYSTEMS COMMITTEE MEETING
JUNE 29 - JUNE 30, 1998

The Quality Systems Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Monday, June 29, 1998, at 1 p.m. Central Daylight Time (CDT), and on Tuesday, June 30, 1998, at 8:30 a.m. CDT, as part of the Fourth NELAC Annual Meeting in San Antonio, TX. The meeting was led by its chair, Ms. Sylvia Labie of the Florida Department of Environmental Protection. A list of action items is given in Attachment A. A list of participants is given in Attachment B.

INTRODUCTION

Ms. Labie called the meeting to order by introducing the members of the committee, including incoming members, and recapping the committee's goals for the preceding year. Outgoing committee members are Ms. Labie and Mr. Steve Getz. Incoming members are Mr. David Mendelson and Mr. Jeff Nielsen. Over the past year the standards have been refined and clarified. The Quality Systems Committee has made a commitment to performance based measurement systems (PBMS). Ms. Labie emphasized that the standards are a work in progress, and explained the NELAC process for making substantive changes to the standards. She also explained the well-defined "rules of the road" for making comments and participating in discussion during the committee meeting. Ms. Labie announced that she had tried to schedule most of the major issues bridging the Quality Systems and On-Site Assessment Committees during the opening day's meeting so that members of the On-Site Assessment Committee would be able to attend.

REVIEW OF PROPOSED CHANGES TO STANDARDS

- Section 5.0 - Introduction - Proposed changes to the introductory language met with little discussion. Proposed additions to Section 5.1 (Scope) have been withdrawn by the committee.

- Section 5.4.2e - Committee wasn't sure how to make it an auditable standard. Will restore the language and add clarifying language later.

- Section 5.5 - Quality System-added "test" to the term "methods" where they meant test methods. This was a global change. 5.5.3.1,5.5.3.2, 5.5.3.3 may need to be clarified as per ISO standards. Will review current language against ISO.

- Section 5.5.3.1- Qualifications of Auditors-leave the word "qualified" in.

- Section 5.5.3.2 - Managerial Review - Managerial review generated some discussion. One attendee asked whether managerial review records made available to the assessor would also become part of the public record. It was noted that the laboratory could reserve the right to petition that managerial review records which contained sensitive information be declared confidential business information (CBI).

- Section 5.5.3.5 - Corrective Action - It was suggested that the words “and quality control” be added to the proposed corrective action language change for clarification.

- Section 5.6.2 - Laboratory Management Responsibilities - There was considerable discussion of analyst training. Discussion centered around clarification of language pertaining to the ongoing demonstration of analyst training and the maintenance of training records. An attendee noted that “the employee file” might include documents which do not concern analyst training and which should not be made public record. For this reason, “the employee file” was changed to “a file.”

- Section 5.6.2.a - Last sentence. The meaning of “chemically transferring reagents” was questioned. Language changed to “aseptic or quantitative techniques.”

- Section 5.7 - Physical Facilities-Accommodation and Environment-most were reworded for clarification. There were no comments on these changes.

- Section 5.8 - Equipment and Reference Material-There were no comments on this section.

- Section 5.9.3.a Restore the word “not.” Strike “for no other purpose.”

- Section 5.9.3c - Restore strike out wording

- Section 5.9.4.1 Change the wording to “Each calibration shall be dated and labeled with or traceable to the method, instrument...”

- Section 5.9.4.3d Instrument Calibration - A lengthy discussion ensued regarding this. It was observed that this standard was no longer consistent with the changes in D.1.4.c. The chair proposed to do the following. Strike out entire standard. Replace with “For results to be reported as quantitative (i.e., those > 3.18 times the Method Detection Limit (MDL)) they must be bracketed by calibration or calibration verification standards. All other results must be reported as having a lower confidence level.” Committee member mentioned that between NELAC IV and NELAC V the committee will be addressing this issue in much more detail.

- Section 5.9.4.1 - Calibration - General Requirements - In response to a question of ISO 9000 instrument calibration, the committee pointed out that this section really pertains to the standardization of methods and acknowledged the dichotomy of language.

- Section 5.9.4.2 - Acceptance Criteria for Support Equipment - Attendees had questions of nomenclature and of frequency of calibration or accuracy checks. There was some discussion of what corrective actions would be taken if equipment failed an accuracy check.

- Section 5.9.4.4.2.c - Continuing Calibration Verification - The implied meaning of the new language is that a second acceptable calibration curve should be obtained if measures failed to correct the problem. It was agreed that the second calibration check should be

performed within the QC window of the method and before further sample analysis is performed.

- Section 5.10.1.a. - Strike out language will be restored to address a member of the audience's concerns regarding SOPs

- Section 5.10.2.1 - Method Validation - There was considerable discussion of the definition of "matrix" in Section d. A committee member asked if a separate method performance must be completed for each individual matrix if a method can be applied to more than one given matrix, i.e. water and soil, or soil and air. The committee considered substituting the word "medium" for "matrix" and changing language in Section C.1.b to read "clean matrix appropriate to the medium." Members expressed the desire to read glossary definitions of medium before making these changes. For this reason, the item was tabled to be revisited in the next day's meeting. The Committee decided to strike the term matrix in Section 5.10.2.1.d.

- Section 5.10.5 - Documentation and Labeling of Standards and Reagents - The chair explained that the purpose of this section's language changes is to ensure that standards and reagents are properly maintained and verified so that they are neither kept beyond their useability, nor needlessly discarded based on vendor specifications. In response to an attendee's comment that requiring containers to be labeled with disposal date would involve other regulations, the committee decided to delete the disposal date requirement.

- Section 5.10.5.c - There was a question regarding the need to document reagent preparation. The Committee reiterated the importance of documenting these procedures.

- Section 5.11.3 - Sample Receipt Protocols - The language changes to this section reduce the amount of information which must be maintained in the log book. The information that was deleted is still required but may be documented in other records. In discussion of proposed changes to Section 5.11.3.a.2, it was noted that sampling personnel are often separate from analysis personnel even if they are employed by the same entity. Therefore, confirmatory preservation checks upon sample receipt may or may not be redundant when samples have been collected and delivered by laboratory sampling personnel. There was general agreement that a critical question is how quickly the analysis process should begin after delivery of samples to the laboratory. After considerable discussion of sample preservation and the time frame surrounding sample analysis, the committee decided to delete the proposed language change and consider the issue at a later date.

- Section 5.11.4.a.2 - Change second sentence to read "Samples shall be stored in such a manner to prevent cross contamination."

- Section 5.12 - Records - There were no comments on this section.

- Section 5.13 - Laboratory Report Format and Contents - It was noted that the original language comprising Section 5.13.a.3.ii.11, which has been deleted, had come directly from the ISO standard. Attendees expressed some resistance to changing this language.

The committee decided to replace the portions of the deleted language which had come directly from the ISO standard.

- Appendix B Definitions - Consolidate or clarify use of terminology. Specific to only Quality Systems.

- Method Detection Limit - Strike out "Analytical Detection Limit" in parenthesis.

- Analytical Detection Limit - strike out (LD)

- Definition: Limit of Detection - The committee explained that this discussion would be limited to the glossary definition of limit of detection. It was suggested that the term be changed to "level of detection." The committee members indicated that they would take this recommendation under advisement. This is considered a generic term with no numerical value associated with it. It was decided to leave it in as is and clarify it over the next year.

- Appendix C.1.b. - Definition of Medium/Matrix. The four major areas of environmental concern defined as consisting of air, water, solid and biological materials. Chair decided that this issue will be readdressed at the Interim Meeting.

- Appendix C.1.d - Insert the word "sample" after population.

- Appendix D.1.1 - Positive and Negative Controls - Attendees engaged in lengthy discussion of blank contamination level versus method detection limit (MDL). The committee agreed that the issue should be given additional consideration in the coming year.

- Appendix D.1.1.b.2. Chemical Testing - One question regarding the Laboratory Control Sample. Committee emphasized that the LCS is one of the batch acceptance criteria.

- Appendix D - Change order of D1.1.b.1. and D1.1.b.2., change reference in b.2 to be consistent with the change in order.

- Appendix D.1.1.b.3 - add "or when a surrogate is not available."

- Appendix D.1.1.b.4 - strike the parenthetical phrase referring to examples.

- Appendix D.1.4.c - Method Detection Limits - This section gives a committee-derived definition for quantitatively reported results of 3.18 times the MDL. Discussion ensued concerning the use of calibration standards to bracket a quantitatively reported result value. One attendee suggested running a low-level verification standard to demonstrate the ability to analyze samples at that low level rather than bracketing low-level samples with calibration standards. The language was changed to read "...shall be bracketed by calibration or calibration verification standards." It was suggested that a definition for reporting limit be added to the glossary. This was tabled for additional consideration in

the coming year. Several attendees from the regulatory sector noted that once a quantitatively reported result value is above the regulatory level, it no longer matters by how much the value exceeds the regulatory level. Therefore, bracketing the result might be considered a waste of time and money. The committee deleted the entire sentence "Numerical values may be assigned to results below this range, but these must be identified on the final report as having lower associated confidence levels." because this standard was addressed elsewhere.

- Appendix D.2 - Whole Effluent Toxicity-No discussion.

- Appendix D.3.2 - Test Variability/Reproducibility - An attendee questioned how a laboratory could judge a "suspected positive" sample in order to run duplicates. The committee explained that the laboratory should duplicate at least 5% of its samples and would have to make an educated guess as to suspected positives. The point was made that a laboratory often has some inkling of sample content based on previous analyses of samples from the same place. It was also noted that running duplicates to ensure the quality of the process would require the collection of additional samples. One attendee questioned the inclusion of guidance in a requirement document. The committee responded that the auditing procedure is not black and white and that an auditor will have to use some professional judgement. After considerable discussion, the Committee decided to withdraw its proposed change. The statement continues to read, "At least 5% of the suspected positive samples shall be duplicated."

- Appendix D3.3 - Method Evaluation strike out the word "sensitivity" in the last sentence. No other comments.

- Appendix D.4 - Radiochemistry - A request was made concerning blank subtraction for radiochemistry. The committee explained that the original language was vague and the proposed language was consistent with discussion in other sections.

- Appendix D.5 - Air Testing (Report from Subcommittee). Members of this subcommittee are Cliff Glowacki, Susan Kilmer, Mike Poore, Gene Riley, Don Russel, and Hank Taylor. The subcommittee is still searching for an EPA Regional representative. The committee has reviewed all of Chapter 5 and most of their changes are editorial in nature. They have four sections to review in detail and will be looking at the appendices over the next few months.

- A question was raised about the potential need to add an appendix for waste testing. The committee had differing opinions on the necessity of another appendix but will include this concept in further discussions.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE MEETING
JUNE 29 - JUNE 30, 1998

Item No.	Action Item	Date To Be Completed
1.	Committee to read glossary definitions of "medium" in order to decide wording changes (substitution of "medium" for "matrix") for Section 5.10.2.1.	January 1999
2.	Committee to decide if there is a need to exempt preservation checks in certain circumstances and to identify specific standards if required. (Section 5.11.3).	January 1999
3.	Committee to consider substituting "level of detection" for "limit of detection" in Appendix B (Definitions).	January 1999
4.	Committee to consider clarification of language in D.1.1 concerning blank contamination levels which are lower than method detection limit.	January 1999
5.	Committee to determine whether quantitively reported result values above the regulatory level should be bracketed by standards.	January 1999
6.	Committee to consider the alternatives to the current MDL requirements and propose changes.	January 1999
7.	Committee to consider other approaches to calibration, and the merits of single point calibration curves and propose changes.	January 1999
8.	Committee to reconsider the time frame for spiking all components of a multi component method.	January 1999
9.	Input from the Air Subcommittee must be completed.	September 1998
10.	Incorporation of Air Subcommittee recommendations.	January 1999
11.	Response to Suburban Water Testing Laboratory, Inc. letter.	July 18, 1998
12.	Consider comments received from April 15 through July 2, 1998.	August 3, 1998

Attachment B

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QUALITY SYSTEMS COMMITTEE MEETING
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